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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,318

03/31/2004

Ron Wortley

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5172

27966

7590

06/09/2009

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,318	<b>Applicant(s)</b> WORTLEY ET AL.	
	<b>Examiner</b> LINDSEY BACHMAN	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 April 2008 has been entered.

### ***Response to Arguments***

Applicant's arguments filed 2 April 2008 have been fully considered but they are not persuasive.

In response to applicant's argument that the cited references do not contain an element described as a tunneler, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 and 26-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims state that the flexible members are of "dissimilar length". It is unclear to the Examiner what difference in length is necessary for the lengths to be considered dissimilar. For the purpose of examination, Examiner will interpret the term "dissimilar length" to mean unequal length.

Claim 13 recites the limitation "the protrusion" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-11, 14, 15, 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (US Patent 6,921,396).**

Claim 1, 5, 14: Wilson'396 discloses a tip (412, 416) that is capable of being gripped and therefore contains gripping means and a plurality of flexible shaft members (419, 423) that extend from the tip having unequal lengths (Figure 12).

Claim 2, 3, 6, 7: Based on its size and shape, the device of Wilson'396 in Figure 12 is capable of being retained in the lumen of a catheter. Further, the device of Wilson'396 is capable of being retained with the use of a protrusion.

Claim 4, 8: Wilson'396 shows that the difference in the lengths of the shaft members is up to 20 percent (Figure 12).

Claim 9: Wilson'396 discloses a tunneler shaft (40) that is removably connected to the tip (412) (Figures 4-7; column 9, lines 48-50).

Claim 10: Wilson'396 discloses a sheath (300) that covers a portion of the tip (412) and tunneler shaft (40) that are connected (column 10, lines 50-55).

Claim 11: The sheath is retained on the tip and tunneler shaft.

Claim 15: Wilson'396 discloses a tip (412, 416) that is capable of being gripped and a plurality of shaft members (419, 423) extending from that have unequal lengths. Wilson'396 also discloses a tunneler shaft (40) removably connected to the tip and made of rigid materials. The tunneler (40) contains a first end (42) that is tapered. There is a sheath (300) that covers the portion of tip and tunneler shaft that are connected (column 10, lines 50-55).

Claim 26: Wilson'396 discloses a tip (412,416) that is capable of being gripped, a tunneler shaft (40) that is rigid and contains a first end (42) that is tapered, and a plurality of flexible tip shaft members (419, 423) extending from the tip and having unequal lengths.

Claim 27: Based on its size and shape, the device of Wilson'396 in Figure 12 is capable of being retained in the lumen of a catheter. Further, the device of Wilson'396 is capable of being retained with the use of a protrusion.

**Claims 21 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Edelman et al. (US Patent 4,626,240).**

Claim 21: Edelman'240 discloses a multi-lumen catheter (5, 5) and a tunneler that contains a tip (2) that is capable of being gripped and a plurality of flexible members (7, 8) extending therefrom having unequal lengths.

Claim 28: Edelman'240 discloses a multi-lumen catheter (5, 5) and a tunneler that contains a tip (3), a plurality of flexible members (7, 8) extending from the tip, and a tunneler shaft (2) that is tapered and rigid (see Figure 1).

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson'396, as applied to Claim 11, and further in view of Wilson et al. (US Patent Application 2002/0099326).**

Wilson'396 teaches the limitations of Claims 12 and 13, except for a retaining ring and protrusion for retaining the sheath on the tip. However, column 11, lines 10-40 of Wilson'396 points to co-pending Application 09/769,052 (US Publication 2002/0099326) which states that it is known to retain sleeves (34, 36) with a protrusion

Art Unit: 3734

(small piece of tape) in order to keep them from sliding off of sliding off element 40. In light of this teaching by Wilson'326, it would be obvious to retain sleeve (300) since Wilson'396 teaches that it is desirable to retain the sleeve during use because it masks any discontinuities at the interface of the tip and shaft (column 10, line 51 to column 11, line 10).

**Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson'396, as applied to Claim 15, in view of Delaloye (US Patent 6,165,167).**

Claim 16, 19, 20: Wilson'396 teaches the limitations of Claim 16 except for protrusions on the shaft members.

Delaloye'167 teaches that it is old and well known to provide a protrusion on a shaft member for the advantage of retaining the shaft within a sleeve containing a recessing retaining ring (column 2, lines 52-64). It would have been obvious to one of ordinary skill in the art to modify the shaft members of Wilson'396 so that it too has this advantage.

Claim 17: The sheath (300) is retained on the tip (412, 416) and the tunneler shaft (40) (column 10, lines 50-55).

Claim 18, 19, 20: Wilson'396 teaches the limitations of Claims 18, except for a retaining ring for retaining the sheath on the tip. However, column 11, lines 10-40 of Wilson'396 points to co-pending Application 09/769,052 (US Publication 2002/0099326) which states that it is known to retain sleeves (34, 36) with a protrusion (small piece of tape) in order to keep them from sliding off of sliding off element 40. In light of this teaching by Wilson'326, it would be obvious to retain sleeve (300) since Wilson'396

Art Unit: 3734

teaches that it is desirable to retain the sleeve during use because it masks any discontinuities at the interface of the tip and shaft (column 10, line 51 to column 11, line 10).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Application/Control Number: 10/814,318  
Art Unit: 3734

Page 8

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